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Title: Informed Consent and Public Disclosure of Part IV ABMS MOC Research Projects on Human Subjects

Introduced by: Domenic Federico, MD, for the Kent County Delegation

Original Author: Megan Edison, MD

Referred to: Reference Committee E

House Action: **REFER**

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Whereas, a required component of the American Board of Medical Specialties (ABMS) Maintenance of Certification (MOC) program is the Part IV "Practice Improvement Module," and

Whereas, medical ethics recognize that patients have a right to know the inherent risks and benefits of their medical care, and

Whereas, informed consent is the ethical process of informing patients that the care they are receiving is under investigation, is part of an investigation, and may or may not be the best practice, and

Whereas, medical ethics requires that studies involving patients requires informed consent and review process by an independent board, and

Whereas, federal Department of Health and Human Services' guidelines regarding "practice improvement modules" have allowed a gray zone for informed consent, and

Whereas, this "gray zone" has allowed Part IV MOC research on human subjects without consent, under the guise of "practice improvement" rather than research, and

Whereas, these Part IV research projects have subjected patients to additional visits, additional pressure to obtain vaccinations and the withholding of medical procedures, and

Whereas, physicians have conscripted patients into these Part IV projects without informed consent and have published this data, and

Whereas, historically government permission for medical research on human subjects has not always reflected our highest ethical standards, and

Whereas, physicians should hold ourselves to a higher ethical standard than government sanction; therefore be it

RESOLVED: That the Michigan Delegation to the American Medical Association (AMA) ask our AMA to amend the AMA Principles of Maintenance of Certification (MOC), Maintenance of Certification H-275.924, by addition (**bold type**) as follows:

**16. In regards to MOC Part IV, our AMA expects the American Board of Medical Specialties (ABMS) and ABMS Member Boards to hold the highest ethical standards when engaged in clinical research for the purposes of "practice improvement" including but not limited to the imposition of the requirement that any physician engaged in an MOC Part IV "Practice Improvement Module" activity that alters the usual care of his/her patients by frequency of visits, use of a medication, use of a procedure, or recommendation of a vaccine**

55 shall only include those patients from whom he or she has obtained informed consent (or  
56 consent from the patient's lawfully authorized nominee) that is neither pressured nor coerced.  
57 In obtaining such consent, patients and their families shall be provided with sufficient  
58 information and time to fully comprehend any risks and/or benefits of participation in the MOC  
59 Part IV activity.; and be it further

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61 RESOLVED: That the Michigan Delegation to the American Medical Association (AMA) ask our  
62 AMA to amend AMA policy, Maintenance of Certification and Osteopathic Continuous Certification D-  
63 275.954, by addition (**bold type**) as follows:

64 **36. Call upon the American Board of Medical Specialties (ABMS) and ABMS Member**  
65 **Boards to require any physician engaged in a MOC Part IV "Practice Improvement Module"**  
66 **activity that alters the usual care of his/her patients by frequency of visits, use of a medication,**  
67 **use of a procedure, or recommendation of a vaccine to obtain informed consent from his or her**  
68 **patients (or consent from the patient's lawfully authorized nominee) who are included in such**  
69 **activity. In obtaining such consent, patients and their families shall be provided with sufficient**  
70 **information and time to fully comprehend any risks and/or benefits of participation in the MOC**  
71 **Part IV activity and their consent shall not be subject to pressure or coercion. 37. Encourage the**  
72 **American Board of Medical Specialties (ABMS) and ABMS Member Boards to publicly disclose all**  
73 **active Maintenance of Certification Part IV projects involving human subjects.;** and be it further  
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75 RESOLVED: That the Michigan Delegation to the American Medical Association (AMA) ask our  
76 AMA to amend AMA policy, Informed Consent and Decision-Making in Health Care H-140.989, by  
77 addition (**bold type**) as follows:

78 **(8) A physician engaged in a Maintenance of Certification (MOC) Part IV "Practice**  
79 **Improvement Module" activity that alters the usual care of his/her patients by frequency of**  
80 **visits, use of a medication, use of a procedure, or recommendation of a vaccine shall only**  
81 **include those patients from whom he or she has obtained informed consent (or consent from**  
82 **the patient's lawfully authorized nominee) that is neither pressured nor coerced. In obtaining**  
83 **such consent, patients and their families shall be provided with sufficient information and time**  
84 **to fully comprehend any risks and/or benefits of participation in the MOC Part IV activity.**  
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87 WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE